

Bogota D.C., October 11 2004

Vicki Lotwek

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5100 Paint Branch Parkway

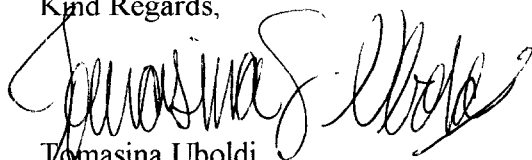
College Park, MD, 20740-3835

VL/FDA

Subject Information requested on plant preparation processes. (Anamu and Vira vira)

In the present package is included the information requested on October 7th, 2004 telephone conference. This includes a brief summary of the process the plant goes through before arriving at Naturasol, and the percentages of plant in each tablet of each plant. I also attached a copy of the S.O.P. (Standard Operative Procedure) formats for both plants, our ISO9001 certificate, and a copy of our certificate of capacity of production expedited by the INVIMA (National Institute of Vigilance of Medicines and Food) each with its pertaining translation. We hope this answers your questions. With nothing further, we remain at your service.

Kind Regards,



Tomasina Uboldi

Department of Exterior Commerce

Anamu

Wild plant, grows in warm climates.

- Parts used. leaves and stems. (cut 10cm above ground)

Process before arriving at Laboratorio Naturasol

- Washed in a solution 15% of calcium hypochlorite and water
- The plant is then double dried in a stainless steel oven at 45° C
- It is then milled in a stainless mill and sifted through a 3 mm sift.
- Then it's pulverized and sifted through a 0.8 mm sift.
- The plant material is double packed in a 25 kg plastic bag with fiber cover.

It is given an internal lot number and shipped to final destination (Laboratorio Naturasol).

After arriving at our installations the plant material:

- goes through an organoleptic inspection by the pharmaceutical chemist.
- Random microbiological tests are done 6 times a month
- It is then stored in the prime materials warehouse
- When a production order is issued it goes through the process described on Standard Operative Procedure format (S.O.P)

Content of New Dietary Supplement: 89% in 500 mg. tablet.

Tablet also contains 9% Starch, 1% Arabic Gum, 1% Magnesium Stereate.

Presentations in bottles of 60, 90 and 120 tablets.

Vira vira

Wild plant, grows mainly in high mountain ranges, cold climates.

- Parts used: leaves and stems. (cut 10cm above ground)

Process before arriving at Laboratorio Naturasol

- Washed in a solution 15% of calcium hypochlorite and water
- The plant is then double dried in a stainless steel oven at 45° C.
- It is then milled in a stainless mill and sifted through a 3 mm sift.
- Then it's pulverized and sifted through a 0.8 mm sift.
- The plant material is double packed in a 25 kg plastic bag with fiber cover.
- It is given an internal lot number and shipped to final destination (Laboratorio Naturasol)

After arriving at our installations the plant material:

- goes through an organoleptic inspection by the pharmaceutical chemist.
- Random microbiological tests are done 6 times a month.
- It is then stored in the prime materials warehouse.
- When a production order is issued it goes through the process described on Standard Operative Procedure format (S.O.P)

Content of New Dietary Supplement: 81.5% in 500 mg. tablet.

Tablet also contains 16% Starch. 1.5% Arabic Gum. 1% Magnesium Stereate.

Presentations in bottles of 60, 90 and 120 tablets.